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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,397	03/09/2004	Robert Falotico	CRD-5068	1881

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EXAMINER	
BERRIOS, JENNIFER A	

ART UNIT	PAPER NUMBER
1619	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/796,397	FALOTICO ET AL.	
	Examiner	Art Unit	
	Jennifer A. Berríos	1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 September 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 6-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 6-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This office action is in response to the reply filed 9/30/2009, wherein claim 1 has been amended.

Claims 1 and 6-11 are currently pending examination.

Claims 2-5 and 12-24 have been cancelled.

Withdrawn of Finality

1. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

Response to Arguments

2. Applicant's arguments, filed 9/30/2009, with respect to 35 USC 112 2nd Paragraph 103 Rejections, the arguments have been fully considered and are persuasive. The rejection of claims 1 and 6-11 has been withdrawn, but new grounds of rejections are presented below.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1, 6-7 and 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell et al (US 2003/0065382), Hossainy et al (WO 03/082368), Eury et al (US 2002/0004676) and Shull et al (WO 96/34003).

Regarding claims 1, 6 and 10: Fischell teaches a stent that is coated with a composition comprising a polymer and one or more anti-restenosis drugs (basecoat matrix) selected from the group consisting of a finite amount of particular drugs

including topoisomerase I inhibitors including adriamycin etoposide, irinotecan and hycamptin (topotecan) as well as rapamycin (abstract; paragraphs [0020] and [0022]). Furthermore the stent is coated with a plastic material selected from parylene, silicone rubber, polyurethane, polyethylene, nylon and PTFE (polytetrafluoroethylene), a fluoro polymer, wherein the anti-restenosis drug is diffused into the plastic coating (claims 2-3 and 7-8).

Eury teaches the use of topoisomerase inhibitors for the prevention of restenosis. The method includes administering a topoisomerase inhibitor on a stent for local administration (Abstract). The topoisomerase inhibitor is selected from camptothecin, irinotecan and topotecan. In one embodiment the polymer stent is loaded with camptothecin, irinotecan or topotecan (Pg 1 [0015]). A second active agent can be co-administered with the topoisomerase inhibitor, such as Paclitaxel (Pg 1 [0017]), well known to those of ordinary skill in the art to aid in the prevention of restenosis (Pg 2 [0022]).

One of ordinary skill in the art would have been motivated to include any combination of the finite number of anti-restenosis drugs suggested by Fischell because they are all art-recognized equivalents used for the same purpose. All references teach coating an implantable medical device with a composition comprising anti-restenosis drugs, thus one skilled in the art would readily look to Fischell for other anti-restenosis drugs or combinations of anti-restenosis drugs as substitutions to achieve the predictable result of generating a medical device with the desired anti-restenosis drugs. A practitioner would have reasonably expected a medical device coated with a

sustained release coating comprising a combination of anti-restenosis drugs such as a topoisomerase I inhibitor, specifically topotecan, camptothecin or irinotecan as taught by Eury, and a rapamycin.

Fischell/Eury fails to teach the stent to comprise a topcoat, comprising a second polymeric material which comprises an acrylic, as recited by instant claim 11.

Hossainy teaches a rapamycin coated stent; wherein the rapamycin is blended with a polymer, such as polyvinylidene fluoride, a fluoropolymer, for the reservoir layer (Pg 8 and 11). Hossainy also teaches forming a barrier layer to reduce the rate of release of rapamycin from the reservoir layer (Pg 15). The barrier layer can be applied on a selected region of the reservoir to form a rate reducing membrane and can be substantially free of active agents. The polymer for the barrier layer can be the same as the selected polymer for the reservoir layer, or suitable choices are ethylene vinyl alcohol, fluoropolymers, etc. In one embodiment, polybutylmethacrylate, a polymer comprising an acrylic, can be used for the barrier layer (Pg 17-18). Hossainy also teaches that medical devices such as stent-grafts, ballon-expandable stents, shunts, artificial heart valves and pacemaker electrodes can be used (32).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to combine the teaching of Fischell/Eury and Hossainy to arrive at the instant invention. One of skill in the art would have been motivated to add a barrier layer, such as polybutylmethacrylate, to the stent coating of Fischell in order to create a rate reducing membrane to reduce the rate of release or delay the time at which the active agent, such as rapamycin and/or rapamycin and topotecan is released

from the layer directly coating the stent, reservoir layer or basecoat matrix. One of skill in the art would have also been motivated to expand the teachings of Fischell to include stent-grafts and the other medical devices taught by Hossainy, in order to create more application variety Finally one of skill in the art would expect reasonable success because both Fischell and Hossainy teach stents comprising polymer coating contained rapamycin alone or in combination with other anti-restenosis agents, whereon the polymer coating containing the active agent can be a fluoropolymer and Fischell teaches that modifications, adaptations and alterations in design can be made.

Regarding claim 9: The examiner takes the position that since Fischell/Hossainy teaches a stent comprising a basecoat with a fluoropolymer and rapamycin and a topcoat comprising an acrylic, the creation of a chemical/physical barrier is an expected property of the stent of Fischell/Hossainy, as the polymeric material is identical to the polymeric material in instant claims 10 and 11.

Fischell/Eury/Hossainy fail to teach the specific concentration of topotecan recited. Shull teaches chemotherapeutic agents, such as camptothecin, being delivered in vivo to fight cancer growth in the body. For in vivo cell inhibition assays, camptothecin was found to have the following 50% cell growth inhibition concentration (Table 4) ranging from 5.74 nm to about 3223.7nm depending on the cell line. It would have been prima facie obvious to one of skill in the art at the time the invention was made utilize topotecan in the concentrations taught by Shull dependent on the desired results. One of ordinary skill in the art would have been motivated to do so because topotecan and camptothecin are art-recognized equivalents, both topoisomerase I

inhibitors, useful on polymeric stents for the treatment of restenosis, furthermore it would have been obvious to vary the concentration of topotecan used depending on the cell line looking to inhibit as Shull teaches that different cell lines require different concentration to achieve 50% inhibition.

8. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell et al (US 2003/0065382), Hossainy et al (WO 03/082368), Eury et al (US 2002/0004676) and Shull et al (WO 96/34003) as applied to claims 1, 6-7 and 9-11 above, and further in view of Evens et al (US 2003/0065346).

Fischell/Hossainy/Eury/Shull teach all the limitations of claim 1, but fail to teach the implantable structure to be an anastomosis device.

Evens teaches implantable medical devices hat may be coated to with therapeutic agents, drugs or compounds that are mixed with biocompatible materials and are affixed to at least a portion of the medical device. Evens teaches that anastomosis devices may be utilized to join biological tissues, and more particularly, joining tubular organs to create a fluid channel. Anastomosis devices may comprise any suitable biocompatible materials, for example, metals, polymers and elastomers. In addition, there are a wide variety of designs and configurations for anastomosis devices depending on the type of connection to be made. Similarly to stents, anastomosis devices cause some injury to the target vessel, thereby provoking a response from the body. Therefore, as in the case with stents, there is the potential for smooth muscle cell proliferation which can lead to blocked connections. Accordingly, there is a need to

minimize or substantially eliminate smooth muscle cell proliferation and inflammation at the anastomotic site. Rapamycin and/or other drugs, agents or compounds may be utilized in a manner analogous to stents as described above. In other words, at least a portion of the anastomosis device may be coated with rapamycin or other drug, agent or compound.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to combine the teaching of Fischell/Hossainy/Eury/Shull and Evens to arrive at the instant invention. One of skill in the art would have been motivated to substitute the stent of Fischell for an anastomosis device, as taught by Evens, as it's obvious to substitute one equivalent medical device for the other to achieve the predictable result of generating a desired medical device, as Evens teaches that anastomosis devices are utilized in a manner analogous to stents. Finally one of skill in the art would expect reasonable success because Fischell/Hossainy/Eury/Shull and Evens both teach implantable medical devices that can be coated with polymers and therapeutic agents such as rapamycin.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer A. Berríos whose telephone number is

(571)270-7679. The examiner can normally be reached on Monday-Thursday: 7:00am-4:00pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (571) 270-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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